

CERTIFICATE

Berlin Cert GmbH



hereby certifies that

WSK Medical B.V.

Science Park 608, Unit C.05, 1098 XH Amsterdam, Netherlands

has implemented and uses a quality management system for the following scope of application

Development, installation and service of an artificial intelligence solution for the detection and classification of ENT endoscopy findings

The audit report no. B-24-117-S-EZ provided confirmation that the requirements in the standard

DIN EN ISO 13485:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

Medical devices - Quality management systems
Requirements for regulatory purposes

have been fulfilled.

Issued: 19.03.2025

Valid from: 19.03.2025

Valid until: 18.03.2028

Dr.-Ing. Peter Diesing

Signature of authorised representative

